



Armed Forces Epidemiological Board Anti-Malarials Subcommittee and Expert Panel

12 April 2004

Timothy S. Wells, Lt Col, USAF, BSC for CDR Margaret Ryan, MC, USN and the Millennium Cohort Study Team



Investigators:
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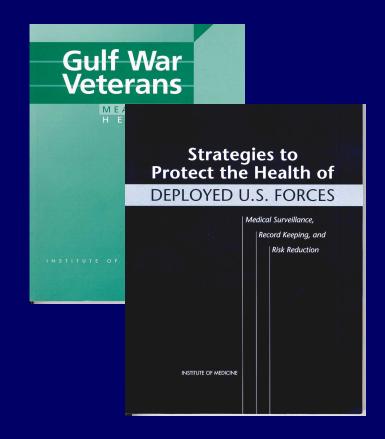
Operational team in San Diego includes many professionals: Gia Gumbs, MPH (coordinator), Suzanne Clark, Thomas Corbeil,

Lesley Henry, Susan Hume, Sheila Jackson, Nick Martin, Robert Reed, MS, Besa Smith, MPH, Tyler Smith, MA, Steven Speigle, Timothy Wells, DVM, PhD, James Whitmer, and Sylvia Young, MD, MPH.

 Section 743 of the 1999 Strom Thurmond Act authorized the US Secretary of Defense to establish a... longitudinal study to evaluate data on the health conditions of members of the Armed Forces...

Institute of Medicine Reports

- Recommended a prospective cohort study of service members.
- Encouraged capitalization on new surveillance and health data, not available at the time of the Gulf War.
- In the model of Framingham and other cohorts, measure deployment impact prospectively.





Primary objective

Assess adjusted risk for development of common chronic diseases of concern (including asthma, diabetes, hypertension, heart disease), as well as chronic multisymptom illnesses within the cohort.

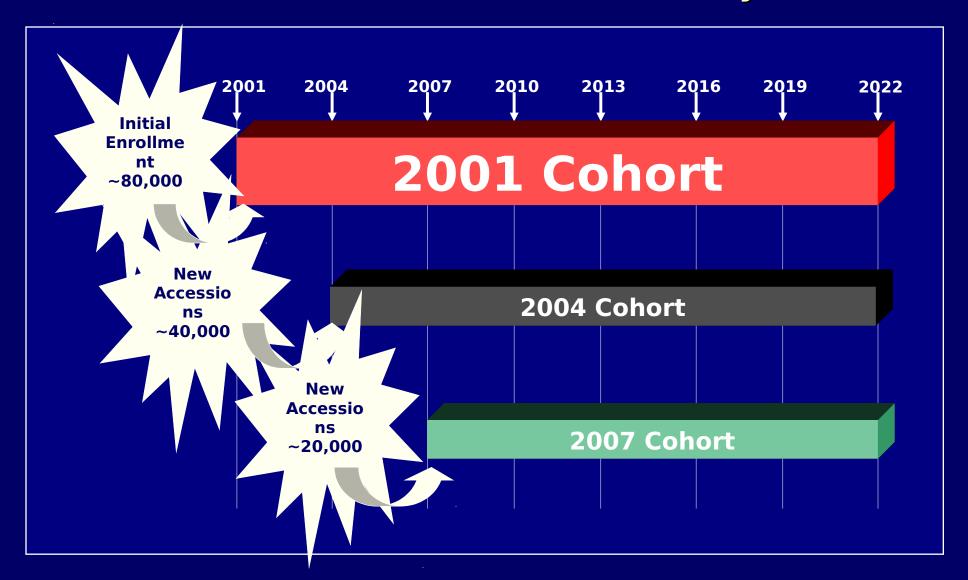
Secondary objectives

Assess functional health status, over time, within the cohort.



<u>Methods</u>

- Enroll a large, stratified random sample of US military personnel on duty as of October 2000.
- Survey at 3-year intervals through 2022.
- In 2004 and 2007, add new accession cohorts.
- Link to other data to assess long-term effects of military exposures.





Some data sets to be linked to core survey data:

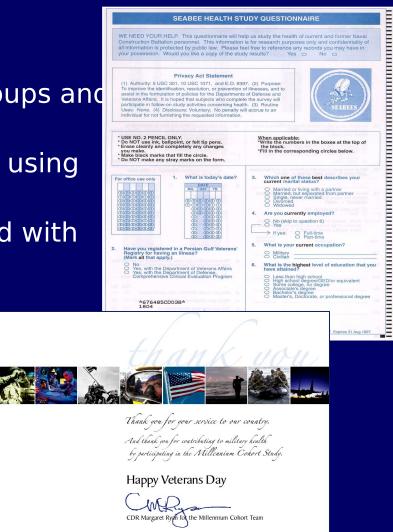
- Demographic and deployment data
- Immunizations
- Outpatient care
- Medications (pharmacy data)
- Hospitalizations
- Birth Registry data
- Veterans disability data
- Mortality data



Induction

Enrollment Methodology

- Using standard instruments, focus groups and pilot testing honed survey.
- Simple, mark-sense form was created using advanced software.
- Modified Dillman methods, augmented with email invitations, are used to enroll.
- Addresses are sought from multiple sources.



www.millenniumcohort.o



Website provides information and option for online enrollment.

- Advanced security and backup features.
- Automatic confirmation emails sent
- "Update address" and other pages facilitate communication.





Prime-MD disorders and syndromes evaluated:

- Somatoform disorder (question 13)
- Depressive syndromes (question 14)
- Panic Syndrome (questions 15 & 16)
- Other Anxiety Syndrome (question 17)
- Alcohol Abuse (question 49)



<u>Short-Form 36 Health Survey scales evaluated:</u>

- General Health (questions 26 & 35)
- Physical Functioning (question 27)
- Role-Physical (question 28)
- Role-Emotional (question 29)
- Social Functioning (questions 30 & 34)
- Bodily Pain (questions 31 & 32)
- Vitality (question 33)
- Mental Health (question 33)



<u>Deployment / War / Casualty:</u> Have you ever been exposed to any of the following? (question 58)

- Witnessing a death due to war, disaster, or tragic event
- Witnessing instances of physical abuse
- Dead and/or decomposing bodies
- Maimed soldiers/civilians
- Prisoners of war/refugees
- Chemical or biological warfare agents
- Other medical countermeasures for chemical or biological...
- Alarms necessitating wear of protective gear



<u>Chemical / Biological:</u> During the past 3 years, were you personally exposed to any of the following? (question 59)

- Occupational hazards requiring personal protective equipment
- Routine skin contact with paints, solvents, substances
- Depleted uranium
- Microwaves
- Pesticides, including creams, sprays, uniform treatments
- Pesticides applied to the environment / living facilities
- Any exposure physical or psychological, during a military deployment that significantly impacted your health



60. Over the <u>past 3 years</u>, did you receive imminent danger pay, hardship duty pay, or combat zone tax exclusion benefits for deployment to any of the regions listed below?

O No	→	Skip to question 63		
O Yes	\longrightarrow	Continue to question 61		

Country Codes			odes		
01	Afghanistan	10	Philippines	19	Arabian Sea
02	Bahrain	11	Qatar	20	Gulf of Aden
03	Croatia	12	Saudi Arabia	21	Gulf of Oman
04	Kuwait or Iraq	13	Serbia (includes Kosovo)	22	Persian Gulf
05	Kyrgyzstan	14	Tajikistan	23	Red Sea
06	Macedonia	15	Turkey	24	Other sea area
07	Montene gro	16	United Arab Emirates		please specify
80	Oman	17	Uzbekistan		
09	Pakistan	18	Other country		
			please specify		



Current status

- Enrollment initiated in Aug 2001
- Enrollment year marked by challenges, including Sep 11th terrorist attacks, anthrax in US mail system in Oct 2001, and US deployments to Afghanistan and Iraq.
- More than 77,000 enrolled to date.
- Complement to 120,000 expected with enrollment in 2004; of 140,000 by 2007.

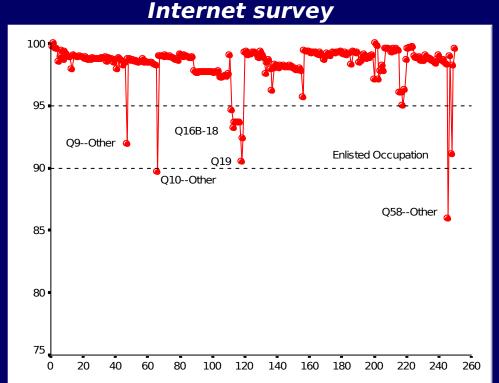
Internet enrollment >50%.

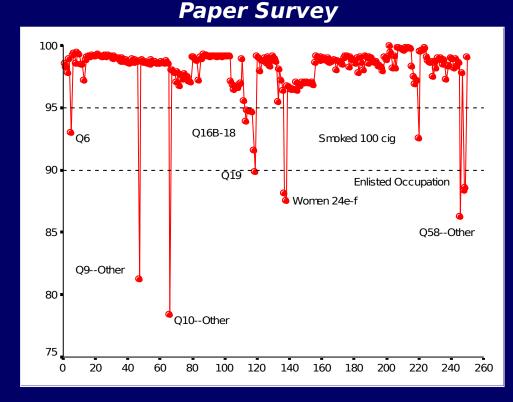
expect total



Intensive Analyses of Data Quality

e.g., question-specific completion rates: internet responders vs. mail responders





Responders versus non-responders and refuser



Responders are more likely to be*:

- Older (OR=1.32 2.67)
- Highly educated (OR=1.10 1.73)
- White race/ethnicity (OR=1.63)
- Female (OR=1.49)
- Married (OR=1.35)
- Army (OR=1.30)
- Officers (OR=1.20)
- Reservists (OR=1.10)
- Past deployers (OR=1.07)
- Working in the fields of communications and intelligence, health care, other technical, and functional support.

<u>Conclusion</u>: Minimal response bias based on demographics, all accounted for in statistical modeling.

* Results of preliminary multivariable logistic regression analyses.



Pilot Study (n=2500) data were linked to military databases to quantify healthcare utilization in the 12 months prior to invitation into the study. (Wellness and obstetric care were excluded)

- Responders averaged 3.3 days of healthcare use (inpatient and outpatient)
- Non-responders averaged 2.9 days of healthcare use.

Difference not statistically significant in multivariable modeling.

<u>Conclusion</u>: No or minimal apparent response bias based on prior health.

Internet responders are more likely to be*:



*Results of

preliminary

- Active duty (versus Reservists) (OR=1.50, Cl 1.44-1.56)
- Male (OR=1.42, Cl 1.36-1.49)
- Race/ethnicity other than black (OR=1.23, Cl 1.16-1.32)
- Married (OR=1.19, CI 1.14-1.25)
- Air Force (OR=1.13, CI 1.07-1.19)
- Ages 25-35
- High school grads or have some college multivariable logistic (versus no degree or advanced degrees)ssion analyses.
- Working in the fields of electronics, communications and intelligence, functional support, or other technical specialty.

<u>Conclusion</u>: Minimal response bias based on preference or access to use of the internet.



Planned analyses and collaborations to date:

<u>Planned and approved</u>:

- An Evaluation of Early Response Bias in the Cohort
- Self-Reported Mental Health Among US Military Personnel, Prior and Subsequent to the Terrorist Attacks of September 11, 2001
- Mental Health Characteristics Among Cohort Members

Future opportunities:

- Self-reported Health Changes After Deployments to US Operation Enduring Freedom and Operation Iraqi Freedom (in development)
- Collaboration interest also expressed by US Centers for Disease Control and Prevention and several universities.
 - Collaborative guidelines have been developed by co-investigators

MILLENNIUM COHORT STUDY

<u>Oversight</u>

- Co-investigators represent all US military services and Veterans Affairs (Drs Amoroso, Boyko, Gackstetter, Gray, Hooper, Riddle, Ryan)
- Protocols designed with external consultation
- Multiple Human Use Review Boards
- External scientific review by
- Annual review by the US Armed
- Millennium Cohort Scientific Committee

Sciences

American Institute of Biological

Forces Epidemiological Board



DoD Center for Deployment Health Research



http://www.nhrc.navy.mil/rsch/code25/program5.htm
http://www.millenniumcohort.org